**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF NEW JERSEY**

| | | |
|---|---|---|
| UNITED STATES OF AMERICA; STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VERMONT, AND WASHINGTON; THE COMMONWEALTHS OF MASSACHUSETTS AND VIRGINIA; AND THE DISTRICT OF COLUMBIA,<br><br>*ex rel.* ZACHARY SILBERSHER,<br><br>*Plaintiffs*,<br><br>vs.<br><br>JANSSEN BIOTECH, INC., JANSSEN ONCOLOGY, INC., JANSSEN RESEARCH & DEVELOPMENT, LLC, and JOHNSON & JOHNSON,<br><br>*Defendants*. | : | Civil Action No. 19-12107 (MEF)(SDA)<br><br>*Document electronically filed* |

**BRIEF OF RELATOR ZACHARY SILBERSHER OBJECTING TO SPECIAL MASTER ORDER (ECF 422) RELATED TO *IN CAMERA* REVIEW OF DOCUMENTS PURSUANT TO THE CRIME-FRAUD EXCEPTION AND MOTION FOR FURTHER *IN CAMERA* REVIEW**

**LITE DEPALMA GREENBERG & AFANADOR, LLC**
Bruce D. Greenberg
570 Broad Street, Suite 1201
Newark, NJ 07102
Tel: (973) 623-3000
Fax: (973) 623-0858
bgreenberg@litedepalma.com

*Attorneys for Plaintiff-Relator Zachary Silbersher*
[Additional Counsel on Signature Page]

# TABLE OF CONTENTS

# TABLE OF AUTHORITIES

## CASES

**RULES**



**STATUTES**

## INTRODUCTION

Relator Zachary Silbersher respectfully submits this memorandum objecting to the Special Master Order filed January 31, 2025 (ECF 422) ("Order") holding, "[w]ith respect to the 50 priority documents designated by Relator for *in camera* review, the Special Master finds no evidence that the crime-fraud exception applies." *Id.* at 2.

Defendants have redacted or withheld over 2,400 documents on the basis of privilege. When initially moving for *in camera* review of a subset of these documents, Relator narrowed the target date range to a period during which he believes the highest concentration of crime-fraud communications occurred. Relator further focused the list to an initial set of 200 of the most promising documents, with the 50 most important designated for priority review. The Special Master initially denied Relator's motion and declined to conduct an *in camera* review of any document (ECF 374). This Court, after reviewing Relator's objections (ECF 393-395) and Defendants' opposition (ECF 413-414), disagreed and ordered a preliminary review of the 50 priority documents "to determine whether the crime-fraud exception applies, and to then make a determination as to whether the remaining documents need to be reviewed . . . ." (ECF 417, at 2.) After conducting a review, the Special Master issued his Order.

Because of the large number of documents for which Defendants assert privilege, Relator can offer only an educated guess for a small subset likely to fall under the crime-fraud exception. Therefore, if the Court determines that any of the 50 priority documents fall under the crime-fraud exception; or if review of the 50 priority documents suggest crime-fraud communications likely exist among the other 200 promising documents, the Court should order review of those 200 documents as well.

## PROCEDURAL BACKGROUND

On May 3, 2024, Relator initially moved for *in camera* review of documents not subject to privilege pursuant to the crime-fraud exception. (ECF 345.) On October 4, 2024, the Special Master denied that motion. (ECF 374.) On October 25, 2024, Relator filed objections to the Special Master's order denying *in camera* review ("Relator's Objections"), in which Relator narrowed the scope of documents requested for an initial *in camera* review to 50 priority documents. (ECF 393-95.) On November 19, 2024, Defendants opposed Relator's Objections. (ECF 413-14.) On December 10, 2024, before Relator's deadline to file his reply to Defendants' opposition, this Court ordered the Special Master to conduct an *in camera* review of the initial 50 priority documents designated by Relator. (ECF 417.) On January 31, 2025, the Special Master issued the Order to which Relator now objects. (ECF 422.)

Relator's October 25, 2024 brief in support of his Objections (ECF 394) provides a detailed explanation of the underlying fraud in this case, including citations to Defendants' internal documents and deposition testimony of its witnesses that were attached to the supporting Declaration of Bruce D. Greenberg. (ECF 395, 395-1 through -6.) To avoid repetition, Relator relies on and incorporates that brief as appropriate.

## STANDARD OF REVIEW

Objections to the findings or conclusions of a Special Master must be reviewed *de novo*. Fed. R. Civ. P. 53(f)(3), (4). In acting on a Special Master's report, "the court must give the parties notice and an opportunity to be heard; may receive evidence; and may adopt or affirm, modify, wholly or partly reject or reverse, or resubmit to the master with instructions." Fed. R. Civ. P. 53(f)(1). Objections to a Special Master's *in camera* review of documents therefore require that the reviewing court perform its own *in camera* review of the designated documents.

**SUMMARY OF DEFENDANTS' FRAUDULENT SCHEME**

Relator refers the Court to Relator's Objections (ECF 394) for a detailed explanation of the fraud, which the Court considered when it ordered the Special Master to conduct his *in camera* review. (ECF 417.) For the sake of brevity, Relator will not rehash the detailed evidence and explanation in this motion. Relator offers below, however, a summary of the important aspects of the fraudulent scheme alleged in Relator's operative Second Amended Complaint (ECF 63) (the "Complaint" or "SAC") that bear on the Court's *in camera* review of the 50 priority documents.

Relator alleges that Defendants caused the United States and Plaintiff States (collectively, the "Government") to pay hundreds of millions of dollars more for Defendants' prostate cancer drug, Zytiga (abiraterone acetate), than they should have. The Government overpaid monopoly prices because Defendants unlawfully obtained a fraudulent patent on Zytiga that they then listed in the Food & Drug Administration's "Orange Book" (*i.e.*, Approved Drug Products with Therapeutic Equivalence Evaluations). By listing the fraudulent patent in the Orange Book and then commencing patent litigation pursuant to the Hatch-Waxman Act, Public Law 98-417 (98th Cong. 1984), Defendants were able to trigger, and then exploit, a 30-month stay of FDA approval for any generic competitor under the Hatch-Waxman Act, which delayed generic entry for years, despite the patent being invalid. *See generally* SAC ¶¶ 42-51; 58; 92-98; ECF 394 at 1-4, 11-19, 16-18, and 25-27; *see also* 21 U.S.C. §§ 355(c)(3)(C), (j)(5)(B)(iii).

The Complaint's basic premise is that when a drug company obtains a patent through fraud, and then asserts that fraudulent patent against generic competitors through regulatory and legal proceedings to keep them off the market, then the patent application itself, as well as every single claim for payment made to Government programs for the drug, is a false claim under the False Claims Act, 31 U.S.C. §§ 3729-33 (the "FCA"), and state FCA analogues. This fraudulent scheme

relies primarily on the analysis and actions of patent counsel, who not only draft, review, and file the fraudulent submissions to the Patent Office, but also implement the fraud to exploit regulatory and legal rules to extend the unlawful patent monopoly for as long as possible, even if they know (or are conscious of a substantial and unjustifiable risk) that the patent eventually will be invalidated. For these reasons, counsel's involvement in obtaining and asserting fraudulent patents makes privilege assertions in these types of cases particularly susceptible to challenge under the crime-fraud exception as compared to the typical lawsuit, where counsel generally becomes involved only *after* the fraud or wrongdoing has already been committed. *Cf. In re Abbott*, 96 F.4th 371, 378 (3d Cir. 2004) (because "the attorneys were key decisionmakers who directed the filing of sham litigation [asserting the challenged patents], it is reasonable to conclude that the attorneys used their own legal research and analysis . . . in furtherance of fraud") (cleaned up).

This case was originally assigned to Hon. Kevin McNulty, who denied Defendants' motion to dismiss. In a thorough and well-reasoned decision, this Court held that Relator's theories of fraud were valid, and the Complaint's allegations sufficiently pleaded that Defendants' representations to the U.S. Patent and Trademark Office in obtaining the subject patent, U.S. Patent 8,822,438 ("the '438 patent"), were fraudulent. *United States v. Janssen Biotech, Inc.*, 576 F. Supp. 3d 212, 228 (D.N.J. 2021), *motion to certify appeal denied*, 2022 WL 225475 (Jan. 26, 2022). Important to the present motion is this Court's determination that Relator adequately alleged false claims based upon the patent application itself, in addition to the downstream claims for payment that incorporated the inflated monopoly price for abiraterone. *Janssen*, 576 F. Supp. 3d at 228-29.

This is because a patent application qualifies as a "claim" under 31 U.S.C. § 3729(b)(2)(A), since it is a "request" for a patent, which is "property."[1]

Several characteristics of the fraud are likely to be implicated in the challenged documents. The gist of the fraud on the Patent Office is this: Zytiga's active ingredient (abiraterone acetate) was originally covered by a patent (the '213 patent), which was scheduled to expire in 2016. To extend the monopoly life of Zytiga past that date, Defendants applied for another patent, which became the '438 patent. The '438 patent claimed a combination of Zytiga's active ingredient (abiraterone acetate) with prednisone. Zytiga is not sold with prednisone; patients must purchase the two drugs separately. The Patent Office repeatedly rejected the combination of the two drugs (abiraterone acetate and prednisone) as obvious, but only allowed the patent after Defendants represented that Zytiga's commercial success rendered the combination patentable. (*See generally* ECF No. 394, at 4-6; SAC, ECF 63 ¶¶ 59-91) Commercial success can be a basis for patentability, but only if the drug's commercial success is directly attributable to the alleged invention (otherwise known as a "nexus" between the drug's success and the alleged invention). *See Brown, & Williamson Tobacco Corp. v. Philip Morris Inc.,* 229 F.3d 1120, 1130 (Fed. Cir. 2000) ("[a] nexus between commercial success and the claimed features is required").

Because abiraterone acetate was already covered by an earlier patent (the '213 patent), that meant that abiraterone already existed in the prior art. Courts have held that "[i]f commercial success is due to an element in the prior art, no nexus exists." *Tokai Corp. v. Easton Enters., Inc.*, 632 F.3d 1358, 1369 (Fed. Cir. 2011); *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1312 (2006) ("[I]f the feature that creates the commercial success was known in the prior art, the

[1] Patents are property. *See, e.g.*, *Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC,* 584 U.S. 325, 334-38 (2018)*; Mission Prod. Holdings, Inc. v. Tempnology, LLC*, 587 U.S. 370, 375 (2019).

success is not pertinent."). As a result, Defendants procured the '438 patent by telling the Patent Office that Zytiga's combination with prednisone was the basis for the drug's commercial success, and *not* the active ingredient in Zytiga itself.

This was a lie. In reality, Defendants knew and believed that Zytiga's coadministration with prednisone was actually a competitive *weakness* impeding the drug's prospects for commercial success. In particular, Defendants believed prednisone to be a weakness against Zytiga's main competitor, Xtandi, which did not require coadministration with prednisone. (*See* Relator's Objections, ECF 394 at 6-10 and 20-23) (Xtandi is also referred to as enzalutamide or MDV3100). Defendants never disclosed this to the Patent Office, but they instead represented the exact opposite.

Moreover, Defendants never disclosed the actual reasons for Zytiga's commercial success. Defendants knew that Zytiga's first-mover advantage and the efficacy of abiraterone acetate, among other reasons, were the principal *strengths* of Zytiga's commercial success. (*See* Relator's Objections, ECF 394 at 9-11 and 20-23; *see also* SAC, ECF 63 ¶¶ 82-88). Defendants never disclosed this to the Patent Office. Moreover, multiple courts have already held that one of the actual reasons for Zytiga's commercial success was because the '213 patent acted as a blocking patent. *See e.g., BTG Int'l Ltd. v. Amneal Pharm. LLC,* 352 F. Supp. 3d 352, 386-87 (D.N.J. 2018); *Amerigen Pharms., Ltd. v. Janssen Oncology, Inc.*, IPR2016-00286, Paper 86 at 39-42 (P.T.A.B. Jan. 17, 2018). Even if a license to the '213 patent was disclosed, Defendants never explained to the patent examiner the import of that license on Zytiga's commercial success.

The '438 patent has been invalidated by both the Patent Trial and Appeal Board (PTAB) and by this Court, and that decision has been affirmed by the Federal Circuit. Defendants' commercial success argument has been explicitly rejected by five separate courts or tribunals: in

three separate *inter partes* review proceedings; once by this Court; and once by the Federal Circuit.[2] Thus, it has been conclusively established that Defendants' June 2013 Submission was false, and the only remaining question is Defendants' scienter (*i.e.*, knowingly false, deliberately ignorant, or reckless). Defendants' scienter includes two aspects relevant to the requested *in camera* review: (1) Defendants knowingly made false statements to the Patent Office regarding Zytiga's commercial success to procure the '438 patent; and (2) Defendants knowingly used that fraudulent patent to exclude generic competition by listing the patent in the Orange Book and asserting the patent in Hatch-Waxman litigation against generic competitors to keep them out of the market.

Several aspects of this fraud are likely to have been furthered by communications involving Defendants' patent prosecution attorneys.

***First***, Defendants knew that their representations to the Patent Office concerning the reason for Zytiga's commercial success was false, because Defendants' own internal documents revealed that their top executives, scientists, physicians, and advisors all believed that prednisone coadministration was a major competitive weakness of Zytiga compared with its major competitors, such as Xtandi (sometimes referred to as enzalutamide or MDV3100), Zytiga's principal competitor. *See generally* pages 6-9 and 20-23 of Relator's Objections (ECF 394). As explained below, any communications indicating that those involved in the patent prosecution, such as Defendants' patent attorneys, had understood prednisone coadministration as being one of

[2] *See Amerigen Pharms. Ltd. v. Janssen Oncology, Inc.*, No. IPR2016-00286, 2018 WL 454509, at *18 (P.T.A.B. Jan. 17, 2018); *Mylan Pharms. Inc. v. Janssen Oncology, Inc.,* No. IPR2016-01332, 2018 WL 456305, at *18 (P.T.A.B. Jan. 17, 2018); *Wockhardt Bio Ag v. Janssen Oncology, Inc.,* No. IPR2016-01582, 2018 WL 456328, at *21 (P.T.A.B. Jan. 17, 2018); *BTG Int'l Ltd. v. Amneal Pharms LLC*, 352 F. Supp. 3d 352, 386 (D.N.J. 2018) (McNulty, J.); *BTG Int'l Ltd. v. Amneal Pharms. LLC*, 923 F.3d 1063, 1076 (Fed. Cir. 2019).

Zytiga's principal weaknesses, but nevertheless allowed the submission of the commercial success argument to the Patent Office, was in furtherance of the fraud.

***Second***, Defendants knew that the real reasons for Zytiga's commercial success had nothing to do with prednisone coadministration, but resulted from other well-known factors, such as (i) the existence of the '213 patent as a blocking patent that excluded generic competitors; (ii) the efficacy of abiraterone acetate as a new treatment compared with legacy treatments; and (iii) Zytiga's first mover advantage against emerging competing treatments, such as Xtandi, which had not yet obtained FDA approval. *See generally* pages 9-11 and 20-23 of Relator's Objections (ECF 394). Defendants were obligated affirmatively to disclose this information because their duty of candor and good faith required them to do so. 37 C.F.R. § 1.56 (pre-AIA) (patent applicants have "duty of candor and good faith," which includes a duty to disclose *all* information "material to patentability"). Therefore, as explained below, communications indicating that those involved in the patent prosecution had understood the actual reasons for Zytiga's commercial success, but chose to omit them in the patent application, were in furtherance of the fraud.

***Third***, Defendants made detailed plans predicting when generic competitors would enter the market as a critical part of their business planning. *See generally* pages 13-16 and 23-25 of Relator's Objections (ECF 394). Therefore, as explained below, communications indicating Defendants' planning for generic entry after the expiration of the '213 patent (in December 2016) and prior to the statutory expiration date of the '438 patent absent invalidation (in 2027) was in furtherance of the fraud. In particular, any projections or loss of exclusivity (LOE) analysis that predicted generic entry prior to 2027—such as in the 2018-2019 time period, when the PTAB, this Court, and the Federal Circuit were expected to, and actually did, invalidate the '438 patent—were made in furtherance of the fraud.

***Fourth***, after the Patent Office notified Defendants that it had decided to grant the fraudulent patent application, Defendants planned, through the advice of counsel, the maximally effective steps to exclude generic competition. This included having the patent issued; wrongfully listing the patent in the Orange Book; and asserting the patent against generic competitors. *See generally* pages 11-13, 16-18, and 25-27 of Relator's Objections (ECF 394). This attorney-driven planning took place between July 3, 2013 (the date of the Patent Office's first Notice of Allowance based solely on Defendants' fraudulent commercial success argument) and September 30, 2014, when counsel listed the '438 patent in the Orange Book. (ECF 394 at 11 & 17).

Relator seeks *in camera* review of emails during this time period—after the patent was granted, and when it was listed in the Orange Book—because Defendants' privilege log indicates that their decisions made during this time period were in furtherance of the fraud (*i.e.*, using the fraudulent patent to exclude generic competition). Defendants' privilege log indicates that the discussions after the patent was allowed appear to have gone up to the highest levels of management and the legal department at Johnson & Johnson. This raises the reasonable inference that discussions concerning the viability of asserting the '438 patent against generics occurred during this time period.

A reasonable inference can be made that these communications analyzed whether to list the '438 patent in the Orange Book (because of its dubious validity) and estimate when the PTAB and the Court would likely invalidate the '438 Patent (to enable Defendants' executives to plan for, and allocate resources to exploit, the unlawful period of exclusivity). If these communications occurred, they would be "in furtherance" of the fraud, and therefore, subject to the crime-fraud exception. *See In re Abbott Lab'ys,* 96 F.4th at 377.

## ARGUMENT

### I. The Third Circuit's Decision in *In re Abbott* Compels the Production of Communications Questioning the Viability of the '438 Patent

The Third Circuit recently held that "the crime-fraud exception applies when attorney advice 'refers . . . to future wrongdoing.'" *In re Abbott*, 96 F.4th 371, 381 (3d Cir. 2004) (quoting *United States v. Zolin*, 491 U.S. 554, 562-63 (1989)). "[W]rongdoings" can "include not only crimes but also torts." *Abbott*, 96 F.4th at 381. Indeed, "[a]ll that is necessary [for the crime-fraud exception to apply] is that the client misuse or intend to misuse the attorney's advice in furtherance of an *improper purpose*. When this occurs, the purpose of the privilege, to promote the fair administration of justice, has been undermined and the privilege no longer applies." *Id.* (quoting *In re Grand Jury*, 705 F.3d 151, 157 (3d Cir. 2012) (emphasis in original)).

The standard for invoking the crime-fraud exception is not a demanding one, and fraud is not required to be proven even by a preponderance of the evidence. An assertion of privilege should be overruled so long as "there is a reasonable basis to suspect" that fraud occurred. *In re Grand Jury*, 705 F.3d at 153. Indeed, "the party opposing the privilege is not required to introduce evidence sufficient to support a verdict of crime or fraud or even to show that it is more likely than not that the crime or fraud occurred." *Id.* at 153-54.

The facts of *Abbott* are instructive here. Abbott sued two prospective generics, Perrigo and Teva, under the Hatch-Waxman Act for infringement of a patent covering Abbott's AndroGel 1% (the '894 patent). Both Perrigo and Teva settled, resulting in a $2 million payment to Perrigo. The Federal Trade Commission subsequently filed an antitrust suit alleging that Abbott's Hatch-Waxman suit against Perrigo was a sham litigation. Discovery revealed that Abbott's attorneys made the ultimate decision to sue Perrigo for infringement of the patent, and the District Court concluded Abbott's counsel "had actual knowledge" that the suit was "baseless" and its sole

purpose was "to impose expense and delay [on] Perrigo." *In re Abbott*, 96 F.4th at 375-77 (citations omitted).

Purchasers of AndroGel 1% then sued Abbott for antitrust claims under the Sherman Act. The purchasers argued that Abbott's patent suit against Perrigo delayed entry of lower-cost generic formulations of AndroGel 1%. During discovery, the purchasers sought to compel production of over 200 documents that they argued "revealed [Abbott's] in-house counsel's views about the baselessness of suing the generic drug manufacturers in the Perrigo lawsuit." *Id.* at 377. The District Court ordered production of 19 documents, and found "it is reasonable to conclude that the attorneys used their own legal research and analysis—the documents at issue here—in furtherance of fraud." *Id.* at 378 (citations omitted).

The Third Circuit affirmed. The court rejected Abbott's argument that the crime-fraud exception only applies to a "deception regarding a material fact." *Id.* at 380. The court also held that the crime-fraud exception carries no reliance requirement—indeed, the fraud requirement of the crime-fraud exception is satisfied even if the client only "intend[ed] to commit a fraud." *Id.* at 382 (citing cases). And the court held the "in furtherance" requirement should be interpreted broadly in connection with the assertion of a patent Defendants know to be fraudulent. In particular, the court zeroed in on documents showing Abbott's counsel "examined statistics about the typical length for patent cases to be resolved in various district courts," and they believed New Jersey would take notably longer than other districts." *Id.* at 383 (citations omitted). In other documents, the attorneys doubted the merits of the action against Perrigo and raised concerns the lawsuit would result in Rule 11 sanctions. *Id.* at 384. In short, the documents showed Abbott's attorneys knew that baseless patent assertions can be used to improperly delay entry of generics, and that was sufficient for the crime-fraud exception to overcome the privilege.

The facts of this case are *a fortiori* to *Abbott*. The wrongdoing in *Abbott* concerned sham litigation—which has stringent standards that the litigation be objectively baseless. *Id.* at 380. In contrast here, the relevant wrongdoing under the FCA has a much lower threshold and does not require that a defendant's claims or statements be objectively baseless. *See United States ex rel. Schutte v. SuperValu Inc.*, 589 U.S. 739, 749 (2023) ("The FCA's scienter element refers to [defendants'] knowledge and subjective beliefs—not to what an objectively reasonable person may have known or believed."). Defendants' actual knowledge is not even required: deliberate ignorance or recklessness suffices. *Id*. at 750 (*citing* 31 U.S.C. § 3729(b)(1)(A) *and* Restatement (Second) of Torts § 526 (1976)). Thus, if Defendants, through their patent attorneys, executives, or agents, were "conscious of a substantial and unjustifiable risk" that their statements to the Patent Office were false but submitted them anyway, FCA liability attaches. *Id.* at 751.

Relator has established a prima facie case that the '438 patent was procured through fraud. (*See* ECF 394 at 6-11.) Moreover, Relator has asked for *in camera* review of documents involving attorney communications after the '438 patent was allowed by the Patent Office—*i.e*., during a critical time period when counsel and management were determining whether their fraudulent patent should be listed in the Orange Book, which would trigger Hatch-Waxman lawsuits in which Defendants would assert the '438 patent, delaying generic entry for years. (*See* ECF 394 at 17-18.)

In *Abbott*, the subject emails indicated a reasonable basis to suspect that the defendants "intended to file a sham litigation for the purpose of preventing" generic entry. *In re Abbott*, 96 F.4th at 383. The same reasoning applies here. If the emails reveal counsel doubting the viability of asserting the '438 patent or otherwise indicating an actual belief or awareness of a "substantial and unjustifiable risk" that the '438 patent would not withstand scrutiny because prednisone

coadministration was not the reason for Zytiga's commercial success, those emails would be discoverable for the same reasons articulated in *Abbott*. *Id.* at 377; *Schutte*, 589 U.S. at 751.

Moreover, the fraud in this case did not end once the '438 patent issued. Listing the patent in the Orange Book and asserting it in litigation to delay generic entry were all attorney-driven steps taken "in furtherance" of that fraud. Communications regarding these aspects of Defendants' conduct would support a good faith belief that Defendants planned and implemented their fraudulent scheme through attorney-driven deliberation and regulatory and legal filings, as well as through financial modeling based on assumptions regarding when Zytiga would lose market exclusivity (because it would no longer be protected by any valid patent). The Third Circuit recognized in *Abbott* that "[i]n this type of situation, in-house attorneys do not just render legal advice; they serve as key decisionmakers that act in furtherance of fraud by implementing the unlawful scheme." *Id.* at 377-78 & 382.

Therefore, under *Abbott*, the Court should order the production of all documents that fall within any of the following categories:

1. Patent counsel's "own legal research and analysis" concerning the use of administrative and judicial procedures to delay generic entry by obtaining issuance of the '438 patent, listing the patent in the Orange Book, and asserting the patent against competitors. *See* ECF 394 at 28.

2. Communications analyzing whether to continue prosecuting the '438 patent without disclosing all facts material to patentability. *See* ECF 394 at 12-13.

3. Communications concerning any decision to submit Defendants' commercial success argument to the Patent Office, or to avoid making a corrective disclosure concerning the real factors driving Zytiga's commercial success, despite an actual belief or awareness of a "substantial and unjustifiable risk" that prednisone was not responsible for Zytiga's commercial success. *See* ECF 394 at 13.

4. Communications indicating awareness of a substantial and unjustifiable risk that the '438 patent would be invalidated. *See* ECF 394 at 13.

5. Communications concerning any Loss of Exclusivity (or LOE) analysis projecting generic entry after December 2016 but prior to the statutory expiration of the '438 patent in 2027. *See* ECF 394 at 14-16, 20, 24.

6. Communications analyzing whether to have the '438 patent issued, listed in the Orange Book, or asserted against competitors despite a belief or awareness of a substantial and unjustifiable risk that the patent would be invalidated. *See* ECF 394 at 17, 18, 20, 25-26, 27.

## CONCLUSION

For the foregoing reasons, Relator respectfully objects to the Special Master's Order (ECF 422). The court should conduct a *de novo* review of the 50 priority documents it previously ordered the Special Master to review *in camera* to determine if any fall under the crime-fraud exception under *In re Abbott Lab'ys*, 96 F.4th 371 (3d Cir. 2024). If the Court determines that any of the 50 priority documents fall under the crime-fraud exception; or if review of the 50 priority documents suggest crime-fraud communications likely exist among the other 200 documents identified by Relator, the Court should order review of those documents as well.

**LITE DEPALMA GREENBERG & AFANADOR, LLC**

Dated: February 21, 2025

*/s/ Bruce D. Greenberg*

Bruce D. Greenberg
570 Broad St, Suite 1201
Newark, New Jersey 07102
Telephone: (973) 623-3000
bgreenberg@litedepalma.com

**HERRERA KENNEDY LLP**
Nicomedes Sy Herrera (*pro hac vice*)
Bret D. Hembd (*pro hac vice*)
1300 Clay Street, Suite 600
Oakland, California 94612
Telephone: (510) 422-4700
NHerrera@HerreraKennedy.com
BHembd@HerreraKennedy.com

**SPARACINO PLLC**
Tejinder Singh (*pro hac vice*)
1920 L Street, NW, Suite 835
Washington, DC 20036
Telephone: (202) 629-3530
tejinder.singh@sparacinopllc.com

**MORGAN & MORGAN**
James Young (*pro hac vice*)
501 Riverside Ave, Suite 1200
Jacksonville, FL 32202
Telephone: (904) 361-0012
JYoung@ForThePeople.com

**MORGAN & MORGAN**
Clark Bolton (*pro hac vice*)
Juan Martinez (*pro hac vice*)
201 N Franklin Street, 7th Floor
Tampa, FL 33602
Telephone: (813) 223-5505
CBolton@ForThePeople.com
JuanMartinez@ForThePeople.com

***Attorneys for Plaintiff-Relator Zachary Silbersher***